

Application Number: 10/554,191  
Reply Dated: December 6, 2010  
Office Action Dated: June 4, 2010

### **REMARKS**

This paper is responsive to the Office Action dated June 4, 2010, for which a three (3) month period of response was given. A Petition and fee for a three (3) month extension of time accompany this paper. Since December 4, 2010 was a Saturday and December 5, 2010 a Sunday, this paper and any accompanying papers are timely filed on Monday, December 6, 2010. Should an additional extension of time and/or any further additional claim fees be due, the Commissioner is hereby authorized to treat this paper as a Petition for any needed extension of time and to charge any fees due to Deposit Account No. 50-0959, Attorney Docket No. 089498.0449.

Claims 1, 2, 5 through 14, 35, 36 and 39 through 48 are pending in the present application. Claims 15 and 17 through 25 were previously withdrawn but are being maintained as Applicants' undersigned representative may seek rejoinder of these claims if permitted under the rules. In light of this, claims 1, 12, 15, 17, 23, 35 and 46 have been amended to more clearly state the nature of the present invention. Additionally, claims 3, 4, 16, 37 and 38 have been cancelled. Furthermore, claims 26 through 34 were previously cancelled as these claims are directed to non-elected inventions. Applicants reserve the right to file one or more divisional applications directed to one or more sets of the non-elected claims at any time permitted under the rules. As such, entry and consideration of the amendments to the claims and the remarks which follow is believed due and is respectfully requested.

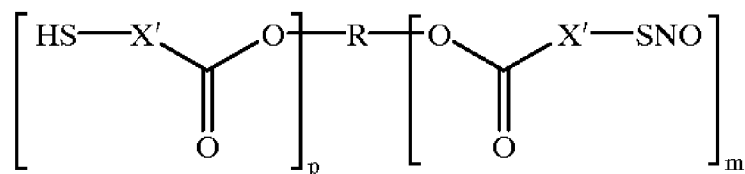
#### **I. Supplemental Information Disclosure Statement:**

Enclosed herewith is a Supplemental Information Disclosure Statement and related fee for same. Entry and consideration of the attached Supplemental Information Disclosure Statement is believed due and is respectfully requested.

#### **II. The 35 U.S.C. § 103(a) Rejections:**

Claims 1, 2, 5, 6, 10, 11, 13, 35, 36, 39, 40, 41, 44, 45 and 47 have been rejected under 35 U.S.C. § 103(a) over Stamler et al. (United States Patent No. 6,232,434).

Stamler et al. discloses polymers derivatized with at least one –SNO group per 1200 atomic mass unit of the polymer. As disclosed therein, the S-nitrosylated polymer has stabilized –S-nitrosyl groups. In another embodiment the S-nitrosylated polymer are prepared by polymerizing a compound represented by the following structural formula:



where R is an organic radical and each X' is an independently chosen from an aliphatic group or substituted aliphatic group. In one instance, each X' is preferably the same and is a C<sub>2</sub> to C<sub>6</sub> alkylene group, more preferably –CH<sub>2</sub>–, –CH<sub>2</sub>CH<sub>2</sub>–, –CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>– or –CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>–. Additionally, p and m are independently a positive integer such that p + m is greater than two. As disclosed in Stamler et al., the polymers disclosed therein can be used to coat medical devices to deliver nitric oxide *in vivo* to treatment sites. The Examiner points to various passages at column 4, line 16 and column 8, lines 4 to 5 as a basis for the proposition that Stamler et al. discloses the fibrous assemblies of the present invention. Applicants respectfully disagree.

As can be seen from independent claim 1, the invention of claim 1 is directed to a fibrous assembly comprising: a first nanofiber that sequesters a first reactive component; and a second nanofiber that sequesters a second reactive component, wherein the first and second nanofibers are prepared by an electrospinning or gas-jet method, wherein at least the first or second nanofiber releases its reactive component when the nanofiber is in the presence of a releasing agent, and wherein when the at least first and second nanofibers release their reactive components, the first and second reactive components react with each other to form a reaction product (emphasis supplied).

Application Number: 10/554,191  
Reply Dated: December 6, 2010  
Office Action Dated: June 4, 2010

As is clear from Stamler et al., Stamler et al. fails to disclose, teach or suggest a fibrous assembly having at least two types of nanofibers therein, each type of nanofiber sequestering a respective reactive component that when exposed to a releasing agent the first and second reactive components react together to form a reaction product. This is because Stamler et al. fails to disclose two different types of nanofibers that each sequester a respective reactive component that are released upon exposure to a releasing agent thereby being able to react with one another to form a reaction product. Accordingly, for at least this reason, Stamler et al. fails to disclose, teach or suggest the fibrous assemblies of claim 1.

Turning to independent claim 35, claim 35 is directed to a fibrous assembly comprising: a first nanofiber that sequesters a first reactive component, wherein the first nanofiber is prepared by an electrospinning or gas-jet method, wherein the first nanofiber releases its reactive component when the nanofiber is in the presence of a releasing agent and the reactive component and the releasing agent react (emphasis supplied).

As is clear from Stamler et al., Stamler et al. fails to disclose, teach or suggest a fibrous assembly having at least one type of nanofiber therein, where such nanofiber sequesters a first reactive component that when exposed to a releasing agent reacts with the releasing agent to form a reaction product. This is because Stamler et al. fails to disclose any type of nanofiber that sequesters a reactive component that is released upon exposure to a releasing agent thereby being able to react with one another to form a reaction product. Accordingly, for at least this reason, Stamler et al. fails to disclose, teach or suggest the fibrous assemblies of claim 35.

Thus, the 35 U.S.C. § 103(a) rejection of claims 1, 2, 5, 6, 10, 11, 13, 35, 36, 39, 40, 41, 44, 45 and 47 over Stamler et al. is believed to be unfounded, and withdrawal thereof is believed due and is respectfully requested. Additionally, it would seem that the Examiner has ignored the obvious differences between the claimed invention and Stamler et al. As is well settled, differences between the cited art and the claimed invention cannot be ignored. Given this, it is believed that a *prima facie* case of obviousness is lacking.

Application Number: 10/554,191  
Reply Dated December 6, 2010  
Office Action Dated: June 4, 2010

Therefore, for at least these additional reasons, Stamler et al. cannot render obvious the fibrous assemblies recited in claims 1 and 35. As such, the 35 U.S.C. § 103(a) rejection of claims 1, 2, 5, 6, 10, 11, 13, 35, 36, 39, 40, 41, 44, 45 and 47 over Stamler et al. is believed to be unfounded, and withdrawal thereof is believed due and is respectfully requested.

Claims 3, 4, 37 and 38 have been rejected under 35 U.S.C. § 103(a) over Stamler et al. (United States Patent No. 6,232,434), as applied to claims 1, 2, 5, 6, 10, 11, 13, 35, 36, 39, 40, 41, 44, 45 and 47, and further in view of Chu et al. (United States Patent No. 6,685,956). The teachings and shortcomings of Stamler et al. are discussed above in detail.

Chu et al. discloses biodegradable and/or bioabsorbable fibrous articles that can be formed from electrospun fibers of biodegradable and/or bioabsorbable fiberizable material. However, as is clear from the disclosure contained therein, Chu et al. fails to cure the deficiencies of Stamler et al. This is because Chu et al. also fails to disclose, teach or suggest the fibrous assemblies of claims 1 and 35. As is detailed above, neither Stamler et al. nor Chu et al. disclose, teach or suggest the fibrous assemblies of the present invention where either: (i) a first and second nanofiber each sequester a respective reactive component that when exposed to a releasing agent react together to form a reaction product; or (ii) a first nanofiber that sequesters a reactive component that when exposed to a releasing agent reacts with such releasing agent to form a reaction product.

Accordingly, for at least this reason, the combination of Stamler et al. and Chu et al. fails to disclose, teach or suggest the fibrous assemblies of claims 1 and 35. Thus, the 35 U.S.C. § 103(a) rejection of claims 3, 4, 37 and 38 over the combination of Stamler et al. and Chu et al. is believed to be unfounded, and withdrawal thereof is believed due and is respectfully requested.

Claims 7, 14 and 48 have been rejected under 35 U.S.C. § 103(a) over Stamler et al. (United States Patent No. 6,232,434), as applied to claims 1, 2, 5, 6, 10, 11, 13, 35, 36, 39, 40, 41, 44, 45 and 47, and further in view of Trescony et al. (United States Patent No.

Application Number: 10/554,191  
Reply Dated December 6, 2010  
Office Action Dated: June 4, 2010

5,994,444). The teachings and shortcomings of Stamler et al. are discussed above in detail.

Trescony et al. discloses a polymeric material formed from a biodegradable polymer matrix that is impregnated with a nitric oxide donor for continuous release of nitric oxide upon hydration. However, as is clear from the disclosure contained therein, Trescony et al. fails to cure the deficiencies of Stamler et al. This is because Trescony et al. also fails to disclose, teach or suggest the fibrous assemblies of claims 1 and 35. As is detailed above, neither Stamler et al. nor Trescony et al. disclose, teach or suggest the fibrous assemblies of the present invention where either: (i) a first and second nanofiber each sequester a respective reactive component that when exposed to a releasing agent react together to form a reaction product; or (ii) a first nanofiber that sequesters a reactive component that when exposed to a releasing agent reacts with such releasing agent to form a reaction product.

Accordingly, for at least this reason, the combination of Stamler et al. and Trescony et al. fails to disclose, teach or suggest the fibrous assemblies of claims 1 and 35. Thus, the 35 U.S.C. § 103(a) rejection of claims 7, 14 and 48 over the combination of Stamler et al. and Trescony et al. is believed to be unfounded, and withdrawal thereof is believed due and is respectfully requested.

Claims 8 and 42 have been rejected under 35 U.S.C. § 103(a) over Stamler et al. (United States Patent No. 6,232,434), as applied to claims 1, 2, 5, 6, 10, 11, 13, 35, 36, 39, 40, 41, 44, 45 and 47, and further in view of Santerre et al. (United States Patent No. 5,798,115). The teachings and shortcomings of Stamler et al. are discussed above in detail.

Santerre et al. discloses pharmacologically-active polymeric compounds that can be coated on a substrate and to a method for providing pharmacological agents in response to *in vivo* activation at a desired location in a mammal. However, as is clear from the disclosure contained therein, Santerre et al. fails to cure the deficiencies of Stamler et al. This is because Santerre et al. also fails to disclose, teach or suggest the fibrous assemblies of claims 1 and 35. As is detailed above, neither Stamler et al. nor Santerre et

Application Number: 10/554,191  
Reply Dated: December 6, 2010  
Office Action Dated: June 4, 2010

al. disclose, teach or suggest the fibrous assemblies of the present invention where either: (i) a first and second nanofiber each sequester a respective reactive component that when exposed to a releasing agent react together to form a reaction product; or (ii) a first nanofiber that sequesters a reactive component that when exposed to a releasing agent reacts with such releasing agent to form a reaction product.

Accordingly, for at least this reason, the combination of Stamler et al. and Santerre et al. fails to disclose, teach or suggest the fibrous assemblies of claims 1 and 35. Thus, the 35 U.S.C. § 103(a) rejection of claims 8 and 42 over the combination of Stamler et al. and Santerre et al. is believed to be unfounded, and withdrawal thereof is believed due and is respectfully requested.

Claims 9 and 43 have been rejected under 35 U.S.C. § 103(a) over Stamler et al. (United States Patent No. 6,232,434), as applied to claims 1, 2, 5, 6, 10, 11, 13, 35, 36, 39, 40, 41, 44, 45 and 47, and further in view of Anand et al. (Ion-Exchange Resins: Carrying Drug Delivery Forward, DDT, Vol. 6, No. 17, September 2001). The teachings and shortcomings of Stamler et al. are discussed above in detail.

Anand et al. discloses ion exchange resins, or ionic polymer networks, as drug-delivery systems (DDSs). However, as is clear from the disclosure contained therein, Anand et al. fails to cure the deficiencies of Stamler et al. This is because Anand et al. also fails to disclose, teach or suggest the fibrous assemblies of claims 1 and 35. As is detailed above, neither Stamler et al. nor Anand et al. disclose, teach or suggest the fibrous assemblies of the present invention where either: (i) a first and second nanofiber each sequester a respective reactive component that when exposed to a releasing agent react together to form a reaction product; or (ii) a first nanofiber that sequesters a reactive component that when exposed to a releasing agent reacts with such releasing agent to form a reaction product.

Accordingly, for at least this reason, the combination of Stamler et al. and Anand et al. fails to disclose, teach or suggest the fibrous assemblies of claims 1 and 35. Thus, the 35 U.S.C. § 103(a) rejection of claims 9 and 43 over the combination of Stamler et al. and

Application Number: 10/554,191  
Reply Dated: December 6, 2010  
Office Action Dated: June 4, 2010

Anand et al. is believed to be unfounded, and withdrawal thereof is believed due and is respectfully requested.

Claims 12 and 46 have been rejected under 35 U.S.C. § 103(a) over Stamler et al. (United States Patent No. 6,232,434), as applied to claims 1, 2, 5, 6, 10, 11, 13, 35, 36, 39, 40, 41, 44, 45 and 47, and further in view of Keefer et al. (United States Patent No. 5,650,447). The teachings and shortcomings of Stamler et al. are discussed above in detail.

Keefer et al. discloses methods for the amelioration, treatment and prevention of restenosis and related disorders. As disclosed therein, such methods involve the administration of nitric oxide by a nitric oxide delivery means comprising a restenosis-ameliorating or therapeutically/prophylactically effective amount of either a polymer to which is bound a nitric oxide-releasing  $\text{N}_2\text{O}_2^-$  functional group a compound comprising a nitric oxide-releasing  $\text{N}_2\text{O}_2^-$  functional group. However, as is clear from the disclosure contained therein, Keefer et al. fails to cure the deficiencies of Stamler et al. This is because Keefer et al. also fails to disclose, teach or suggest the fibrous assemblies of claims 1 and 35. As is detailed above, neither Stamler et al. nor Keefer et al. disclose, teach or suggest the fibrous assemblies of the present invention where either: (i) a first and second nanofiber each sequester a respective reactive component that when exposed to a releasing agent react together to form a reaction product; or (ii) a first nanofiber that sequesters a reactive component that when exposed to a releasing agent reacts with such releasing agent to form a reaction product.

Accordingly, for at least this reason, the combination of Stamler et al. and Keefer et al. fails to disclose, teach or suggest the fibrous assemblies of claims 1 and 35. Thus, the 35 U.S.C. § 103(a) rejection of claims 12 and 46 over the combination of Stamler et al. and Keefer et al. is believed to be unfounded, and withdrawal thereof is believed due and is respectfully requested.

Application Number: 10/554,191  
Reply Dated December 6, 2010  
Office Action Dated: June 4, 2010

III. Conclusion:

Accordingly, reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejection are believed due and is respectfully requested.

For at least the foregoing reasons, claims 1, 2, 5 through 14, 35, 36 and 39 through 48 of the present application are believed to be in condition for allowance, and a Notice of Allowance is respectfully requested.

Should the Examiner wish to discuss any of the foregoing in more detail, the undersigned attorney would welcome a telephone call.

Respectfully submitted,

/Joseph J. Crimaldi/

Joseph J. Crimaldi, Reg. No. 41,690  
Roetzel & Andress  
222 South Main St.  
Akron, Ohio 44308  
(330) 376-2700

December 6, 2010